IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

OPPENHEIM PRAMERICA ASSET MANAGEMENT S.A.R.L., on behalf of itself and others similarly situated, Plaintiffs,	§	
v.	§	CIVIL ACTION NO. H-06-3022
ENCYSIVE PHARMACEUTICALS, INC., *et al.*, Defendants.	§	

MEMORANDUM AND ORDER

This securities fraud case is before the Court on Defendants' Motion to Dismiss [Doc. # 82], to which Plaintiffs filed their Opposition [Doc. # 83], and Defendants filed a Reply [Doc. # 84]. Based on the Court's review of Plaintiffs' Consolidated Class Action Complaint ("Complaint") [Doc. # 76] and all other matters of record, and the application of governing legal authorities, the Court **grants** the Motion to Dismiss.

I. BACKGROUND

Defendant Encysive Pharmaceuticals, Inc. ("Encysive") is a biopharmaceutical company. Defendant Bruce Given is Encysive's President and Chief Executive Officer, and Defendant Richard Dixon is its Chief Scientific Officer. Defendant Stephen Mueller and Defendant Terrence Coyne were each Encysive's Vice President

of Finance, Secretary, and Treasurer during various portions of the relevant time frame. Defendant Gordon Busenbark was Encysive's Chief Financial Officer. Given and Dixon are also members of Encysive's Board of Directors.

Lead Plaintiff Oppenheim Pramerica Asset Management S.a.r.l ("OPAM") is a European fund management company that purchased shares of Encysive stock during the Class Period between February 19, 2004 and July 24, 2006.

Encysive developed a drug called sitaxentan, to be marketed under the trade name "Thelin," for the treatment of Pulmonary Arterial Hypertension ("PAH"). Encysive applied for approval from the Food and Drug Administration ("FDA") and from regulatory authorities in Europe, Canada, and Australia. Approval was granted in Canada, in Australia, and in Europe for all twenty-seven countries in the European Union. During the Class Period, the FDA issued two letters stating that Thelin is "approvable," but the agency has not yet given final approval for Encysive to market Thelin in the United States.[1] The FDA has not, however, denied approval of Thelin.

OPAM, for itself and on behalf of other similarly situated investors in Encysive stock during the Class Period, filed this Complaint alleging that Encysive engaged in securities fraud in violation of § 10(b) of the Securities Exchange Act, 15 U.S.C.

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[1] These letters were issued on March 24, 2006, and July 24, 2006. On July 15, 2007, the FDA issued a third "approvable" letter.

§ 78j(b), and Rule 10b-5 promulgated thereunder. Plaintiffs assert that Encysive made false and misleading statements during the Class Period that caused the price of Encysive stock to be artificially inflated. Plaintiffs also assert a claim against the individual Defendants as controlling persons under § 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a).

Defendants filed their Motion to Dismiss. The Motion has been fully briefed and is now ripe for decision.

II. STANDARD FOR MOTION TO DISMISS

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to seek dismissal of a claim if it fails to "state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). A securities fraud cause of action can fail to state a "claim upon which relief can be granted" if the plaintiff fails to plead each element with particularity. *See Central Laborers' Pension Fund v. Integrated Elec.*, __ F.3d __, 2007 WL 2367776, *2 (5th Cir. Aug. 21, 2007). The United States Supreme Court has made clear that a plaintiff is obligated to provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, __ U.S. __, 127 S. Ct. 1955, 1964-65 (2007) (citing *Papasan v. Allain,* 478 U.S. 265, 286 (1986) (on a motion to dismiss, courts

"are not bound to accept as true a legal conclusion couched as a factual allegation")).[2] "Factual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 127 S. Ct. at 1965. "Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only fair notice of the nature of the claim, but also grounds on which the claim rests." *Id.* at 1965 n.3 (internal quotation marks omitted). When the Complaint contains inadequate factual allegations, "this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id.* at 1966. "[A] district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Id.* at 1967 (quoting *Associated Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 528 n.17 (1983)).

III. ANALYSIS

In order to state a claim for securities fraud under § 10(a) of the Securities Exchange Act, "a plaintiff must allege, in connection with the purchase or sale of securities[:] (1) a misstatement or an omission (2) of material fact (3) made with

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[2] *Twombly* was decided under the less stringent pleading requirements of Rule 8(a) of the Federal Rules of Civil Procedure. Because the Private Securities Litigation Reform Act ("PSLRA") requires that each element of the securities fraud claim be pled with particularity similar to the more onerous pleading requirements of Rule 9, the Supreme Court's decision in *Twombly* applies with at least equal force to the PSLRA pleading requirements.

scienter (4) on which plaintiff relied (5) that proximately [injured him]." *Central Laborers' Pension Fund v. Integrated Elec.*, __ F.3d __, 2007 WL 2367776, *2 (5th Cir. Aug. 21, 2007) (quoting *Fin. Acquisition Partners LP v. Blackwell,* 440 F.3d 278, 286 (5th Cir. 2006)). The Private Securities Litigation Reform Act ("PSLRA") requires that each element be pled with particularity. *See id.*

A. Material Misstatement or Omission

Defendants argue that Plaintiffs have not alleged with adequate particularity a material misstatement or omission. "[I]f an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." *Id.* "Failure to do so results in dismissal of the complaint." *Id.*

Plaintiffs identify statements made during the Class Period by Defendants in press releases, corporate reports, and conference calls with analysts. Many of the statements relate to the clinical studies of Thelin and a comparison of Thelin to a competing drug bosentan, marketed as Tracleer. For example, in press releases during the summer of 2004, Encysive described the continuing clinical program for Thelin. In press releases during the fall of 2004, Encysive compared Thelin with Tracleer and expressed the belief that Thelin "has the potential" to be an important alternative for patients who developed liver problems when using Tracleer. Encysive

continued to report the status and ultimate results of clinical testing throughout the remainder of 2004 and all of 2005.

There is no allegation that Encysive falsified or misstated the status and results of the various clinical tests involving Thelin. Indeed, Encysive fully disclosed problems that were encountered with Thelin's efficacy and safety at different dosage levels. Instead, Plaintiffs allege that these statements were false because the supporting trials were "inadequate." *See, e.g.,* Complaint, ¶¶ 39, 78. Absent any particularized allegation that Encysive knew its trials were fraudulent, the allegation that the trials themselves were inadequate fails to allege a false statement. "[W]here a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study. Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols." *Nathenson v. Zonagen Inc.*, 267 F.3d 400, 420 (5th Cir. 2001).

Other allegedly false or misleading statements Plaintiffs identify in the Complaint relate to Encysive's plan to apply for priority review of Thelin by the FDA and the company's hopes for a successful result. As to many of these statements, however, Plaintiffs fail to allege a factual basis for the conclusory allegation that the statement was false. For example, Encysive issued a press release in February 2005

stating that the company was "focused on filing a New Drug Application (NDA) with the [FDA] in April 2005 to seek marketing authorization." *See* Complaint, ¶ 56. During a conference call that same day, Defendant Given stated that Encysive would "absolutely request priority review." *See id.*, ¶ 57. During an April 2005 conference call, Given noted that cancer and HIV drugs frequently get priority review from the FDA and expressed the view that PAH should get priority review as well because it has a higher mortality rate than HIV and many cancers. *See id.*, ¶ 62. Plaintiffs allege no facts to indicate that these statements were false or that they omitted material information.

The remaining statements identified by Plaintiffs in connection with the FDA application are clearly forward looking projections as to which Defendants enjoy a "safe harbor." "Under Section 21E of the PSLRA, a defendant will not be liable for forward-looking statements, where the forward-looking statement is 'identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.'" *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 866 (5th Cir. 2003) (quoting 15 U.S.C. § 78u-5(A)(ii) ("safe harbor provision"). Meaningful cautionary statements are "company specific warnings based on a realistic description of the risks applicable to the particular circumstances, not merely

a boilerplate litany of generally applicable risk factors." *Southland Securities Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 372 (5th Cir. 2004). To avoid this safe harbor provision, the plaintiff must plead with particularity facts showing that the forward-looking statement was made with actual knowledge that it was false. *See id.* at 371. For example, in the February 2005 conference call referenced above, Defendant Given stated that Encysive believed it had a "good shot" at receiving priority review from the FDA, but noted clearly that it was "an FDA decision of course." *See* Complaint, ¶ 57. During a later conference call in February 2005, Given stated that Encysive did not expect the FDA to require additional clinical trials, but also stated clearly that "you never know what's going to happen when you get into a regulatory process." *See id.*, ¶ 59. Encysive's statements of its expectations regarding the FDA approval process were clearly no more than that – statements of Encysive's hopes and expectations.

Plaintiffs have alleged in bald, conclusory fashion that Defendants knew that Thelin would not obtain FDA approval, would not be commercialized, and would not gain market share from Tracleer. *See id.*, ¶ 78. Plaintiffs have not, however, alleged with any particularity facts supporting Defendants' alleged knowledge. These conclusory assertions of knowledge and falsehoods are insufficient to withstand Defendants' Motion to Dismiss.

Plaintiffs note that Encysive received an "approvable letter" on March 24, 2006, and another one in July 2006. Although Plaintiffs concede that Encysive disclosed the receipt of each letter immediately, Plaintiffs allege that Defendants made misstatements or omissions because they declined to discuss the details of the letters with market analysts. When declining to answer such questions from analysts, Encysive explained clearly that, in order to avoid assisting competitors with their FDA applications, Encysive would keep the details confidential. Encysive's decision not to discuss publicly the details of the "approvable" letters did not constitute a material misstatement or omission.[3]

Plaintiffs have failed as a matter of law to identify any statements by Defendants that constituted misstatements or omissions in support of their securities fraud claims. As a result, Defendants are entitled to dismissal of the Complaint.

B. Scienter

Defendants argue that this case should be dismissed because Plaintiffs have failed to allege scienter with adequate particularity. In any private securities fraud action under the PSLRA, the complaint shall, with respect to each alleged misstatement or omission, "state with particularity facts giving rise to a strong

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[3] Plaintiffs have not alleged and cannot allege that this decision was unreasonable, given the competitive market conditions. During the Class Period, several other companies were testing competing drugs to treat PAH.

inference that the defendant acted with the required state of mind." *Id.* (citing 15 U.S.C. § 78u-4(b)(2)). The plaintiff must allege and prove that the defendant acted with scienter, which means intent or severe recklessness. *Id.* "Severe recklessness is limited to those highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and that present a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it." *Id.*

When determining whether a plaintiff has alleged facts that give rise to the requisite inference of scienter, "a court must consider plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, ___ U.S. ___, 127 S. Ct. 2499, 2510 (2007). "The inference that the defendant acted with scienter need not be irrefutable, *i.e.,* of the smoking-gun genre, or even the most plausible of competing inferences . . . Yet the inference of scienter must be more than merely reasonable or permissible – it must be cogent and compelling, thus strong in light of other explanations." *Id.* (internal citations and quotations omitted). A complaint, therefore, will survive dismissal "only if a reasonable person would deem the inference of scienter cogent

and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

Plaintiffs in this case have not alleged facts that raise an inference that Defendants acted with the necessary scienter. Plaintiffs argue scienter is established by Encysive's failure to disclose "any information about the FDA's refusal to approve Thelin or why it wanted additional clinical trial data." *See* Opposition, p. 17. This argument is rejected. First, the FDA has not refused to approve Thelin and Encysive promptly disclosed the FDA's approvable letters seeking additional information. Second, as is discussed above, Encysive explained its reasons for not discussing publicly the specifics of the FDA letters and that explanation is cogent and compelling. Indeed, it is as reasonable as Plaintiffs' belief that the decision to withhold those specifics constituted knowledge of some misstatement or omission.

Plaintiffs also argue that they have adequately alleged scienter by showing that Encysive was motivated to engage in securities fraud because it needed money from public stock offerings. It is rare that a company conducts a public stock offering for any reason other than to raise money and, therefore, this does not raise an inference of scienter. Additionally, Encysive used a large part of the money it acquired from the stock sales to finance the development of Thelin, indicating Defendants' belief

that Thelin's potential as a successful and lucrative product for the company justified the expenditures.

Moreover, the allegations in the Complaint do not raise an inference of intent or severe recklessness that is at least as compelling as the opposing inference one could draw from the facts alleged. For example, Encysive's applications for approval to market Thelin in Europe, Canada and Australia were approved, supporting Encysive's belief that the FDA application would similarly be approved. Encysive, as early as its 2003 Form 10-K filed in March 2004, clearly and unequivocally cautioned that "[i]f we are unable to clearly demonstrate that Thelin(™) provides an acceptable risk-benefit profile as compared to currently approved therapies, we are not likely to receive regulatory approval to market" the drug. *See* Complaint, ¶ 46. Similar cautionary language was included in the other public statements regarding the clinical testing and the FDA approval process. As is noted above, Encysive invested significant resources in the development of Thelin, indicating its genuine belief that the drug would receive FDA approval and be successfully marketed. The allegations in the Complaint do not support a cogent inference of scienter.

Plaintiffs also note that two of the individual Defendants sold stock during the Class Period. "Insider trading can be a strong indicator of scienter if the trading occurs at suspicious times or in suspicious amounts." *See Central Laborers' Pension*

Fund, 2007 WL 2367776 at *5 (citing *Rubinstein v. Collins,* 20 F.3d 160, 169 (5th Cir. 1994)). "Suspicious in this context generally means that the sales are out of line with prior trading practices or at times calculated to maximize personal profit." *Id.* (citing *Abrams v. Baker Hughes Inc.,* 292 F.3d 424, 435 (5th Cir. 2002)). "Insider trading alone cannot create a strong inference of scienter, but it may meaningfully enhance the strength of the inference of scienter." *Id.* (internal quotations and citation omitted). An insider's sales of only a small percentage of his total stock holdings does not contribute to an inference of scienter. *See id.* In this case, Given, Encysive's CEO and the person who actually made the challenged statements during the press conferences, did not sell any shares during the Class Period. Defendant Mueller sold 17.59% of his holdings and Defendant Dixon sold 13.79% of his holdings. Each had sold shares prior to the Class Period, and each retained the vast majority of their shares throughout the Class Period. Because the sales were of small percentages and only by two insiders, and because there is no other inference of scienter, the stock sales by Mueller and Dixon do not create a cogent inference of scienter.

Absent allegations that raise an inference of scienter that is both cogent and at least as compelling as any opposing inference one could draw from the facts alleged, Plaintiffs' Complaint must be dismissed.

C. Section 20 Control Person Liability

As is discussed above, Plaintiffs have failed to plead with adequate particularity facts to support either the misstatements or the scienter element of a securities fraud cause of action. Because they have failed to allege a primary securities fraud violation, they necessarily fail to state a claim for control person liability under § 20. *See Financial Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 288 (5th Cir. 2006).

IV. CONCLUSION AND ORDER

Plaintiffs have failed to allege with adequate particularity that Defendants made false statements with the necessary scienter. The pleading requirements of the PSLRA and the standard described by the United States Supreme Court in *Twombly* have not been met. The Consolidated Class Action Complaint [Doc. # 76] is itself an amended pleading filed after three civil cases, each with its own complaint, were consolidated. As a result, it appears that additional attempts to amend to plead securities fraud violations in this case would be futile. The Court will not further delay the final resolution of this dispute by allowing yet another amendment. Accordingly, it is hereby

ORDERED that Defendants' Motion to Dismiss [Doc. # 82] is **GRANTED**. The Court will issue a separate Final Dismissal Order.

SIGNED at Houston, Texas, this **18th** day of **September, 2007.**

Nancy F. Atlas
United States District Judge